



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

1306 '02 FEB 12 A9:32
February 8, 2002

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
Suite 600
1050 17th Street, N.W.
Washington, D.C. 20036

Re: Health Claim: Omega-3 Fatty Acids and Coronary Heart Disease (Docket Number 91N-0103)

Dear Mr. Emord:

This letter responds to your letter of November 19, 2001, to Daniel E. Troy, seeking reconsideration of the agency's October 31, 2000 decision in the above captioned matter. You requested that the agency consider the following revised claim and disclaimer:

Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. The scientific evidence supporting this claim is strong but not conclusive.

In a footnote to this claim, you stated, "This claim may be used on any product containing at least 600 mg, but not more than 2000 mg per day of DHA plus EPA."

We have considered your request for your revised claim and disclaimer and are granting it in part and denying it in part, as discussed below,¹ by providing for the following acceptable language:

Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive.

In a follow-up letter to you on February 16, 2001, we discussed including the following introductory sentence in the omega-3 fatty acid claim: "It is known that diets low in saturated fat and cholesterol may reduce the risk of heart disease." The reduction in risk of coronary heart disease (CHD) for the health claims cited in the February 16 letter² is related not only to the

¹Because our decision provides for the use of a shorter claim and disclaimer, as requested, we do not need to address your particular criticisms of the qualified claim in your November 19 letter.

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consumption of the substance itself, but also to consumption of a low saturated fat, low cholesterol diet. In this matter, we did not evaluate whether a possible reduced risk of CHD from the consumption of omega-3 fatty acid dietary supplements is also related to the consumption of such a diet. Therefore, the agency does not intend to consider the exercise of its enforcement discretion to be contingent upon the use of the quoted sentence in connection with the claim and disclaimer set out below. The requirements identified under "Disqualifying levels" in the February 16 letter still apply to this claim.

As we stated in our October 31 letter to you, FDA determined that the scientific evidence for a health claim about the relationship between EPA and DHA omega-3 fatty acids and reduced risk of coronary heart disease (CHD) outweighed the scientific evidence against such a claim. Consistent with the court's decision in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), and our implementation of that decision ("Food Labeling: Health Claims and Label Statements for Dietary Supplements; Update to Strategy for Implementation of *Pearson* Court Decision; 65 Fed. Reg. 59,855 (2000)), we provided for a qualified claim. We also determined that dietary supplements not recommend or suggest in their labeling, or under ordinary conditions of use, daily intakes of more than 2 grams EPA and DHA.

You did not submit anything in your request for reconsideration that would alter our conclusions in the October 31 letter. Further, you did not submit any data or information to support a request for limiting the use of the qualified claim to dietary supplements containing at least 600 mg DHA plus EPA. Thus, we do not agree with that limitation. We continue to consider the exercise of our enforcement discretion to be contingent upon dietary supplement labeling to not suggest or recommend in the labeling, or under ordinary conditions of use, amounts of EPA and DHA omega-3 fatty acids that would exceed 2 grams per day. In fact, we continue to encourage manufacturers to limit recommendations or suggestions of daily intakes in labeling, or under ordinary conditions of use, to 1 gram or less per day of EPA and DHA omega-3 fatty acids for an added safety margin and because of the possibility of benefit at intakes of less than 1 gram per day.

Although we do not agree with the language suggested in your November 19 letter, i.e., that the evidence supporting the claim is "strong," we have concluded that the following statement about the relationship would properly qualify the state of the scientific evidence, and thus, would be acceptable:

fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber may reduce the risk of heart disease"; 101.81(c)(2)(i)(A) "diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods may reduce the risk of heart disease"; 101.82(c)(2)(i)(A) "diets that are low in saturated fat and cholesterol and that include soy protein may reduce the risk of heart disease"; and 101.83(c)(2)(i)(A) "plant sterol/stanol esters should be consumed as part of a diet low in saturated fat and cholesterol."

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Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive.

Thus, the FDA would consider exercising its enforcement discretion on an EPA and DHA omega-3 fatty acid dietary supplement bearing these two sentences, i.e, the claim and disclaimer stated immediately above, provided that the supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding 2 grams per day EPA and DHA. This decision affects the wording of the claim, but does not affect other aspects of our October 31 decision.

If you have any questions about this response to your request for reconsideration, please do not hesitate to contact me to discuss them.

Sincerely,

Christine J. Taylor, Ph.D.
Director
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

cc: Dockets Management Branch (HFA-305)
Daniel E. Troy, Chief Counsel

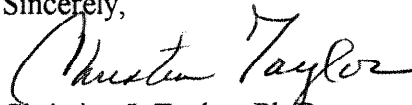
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If you have any questions about this response to your request for reconsideration, please do not hesitate to contact me to discuss them.

Sincerely,

A handwritten signature in black ink, appearing to read "Christine Taylor", written in a cursive style.

Christine J. Taylor, Ph.D.

Director

Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

cc: Dockets Management Branch (HFA-305)
Daniel E. Troy, Chief Counsel